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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/082,247 05/20/98 NADEAU

J F-2821RI

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| EXAMINER |
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HM22/0703

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| HOUTTEMAN, S | |
| ART UNIT | PAPER NUMBER |

1656

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DATE MAILED:

07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/082,247

Applicant(s)

Nadeau et al.

Examiner

Scott Houtteman

Art Unit

1656



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Apr 5, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) 1-20 is/are allowed.

6) ☒ Claim(s) 21-42 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other:

1. The request filed on 4/4/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) is acceptable and a CPA has been established. An action on the CPA follows.

2. Applicant's response, filed 4/5/01, has been carefully considered with the following effect:

The rejection of paragraph 8, of the previous Office action (originally mailed on 12/22/99 and re-mailed on 11/13/00) has been withdrawn in view of applicant's amendment canceling the rejected claims. (102 rejection)

The objections and rejections of paragraphs 3 and 5, of this Office action have been maintained.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 21-42 are rejected under 35 U.S.C. 112, first paragraph. They contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record (new matter).

5. Applicant has amended the claims to add the words "primer-based" and has repeated arguments set forth in the last response filed 5/28/99, briefly that support is found in 6 passages and that the passage warning against the use of PCR leading to "high levels of background

signal,” support the “generic” description and definitions referenced above. Applicant also argues that Strand Displacement Amplification merely exemplified the generic description of primer based nucleic acid amplification reactions in the specification.

The amendment to add “primer-based” does not significantly alter the original claims. Primers are critical to amplification reactions thus amplification reactions are inherently “primer based.”

These arguments are not persuasive. The argument has not established why, if the discussion of amplification is generic, there is no mention of PCR coupled amplification only SDA coupled amplification. Similarly, the argument does not address why the plain meaning of the recited passage, warning about high background when PCR is used, should be disregarded.

The mere recitation of the word “amplification” without the words “strand displacement” does not establish that the specification describes PCR. Rather, the reading of the word “amplification” in context makes clear that this is merely short hand for the phrase “strand displacement amplification.”

6. Claims 21-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record.

7. Applicant argues by giving a “technical explanation” that the “alleged undesirable high levels of background signal are not manifest in a primer based amplification method” and that the method, as claimed “would not cause the undesirable high levels of background signal as asserted in the rejection.” Applicant then gives “support” for this technical explanation in the specification.

This argument is not persuasive. By providing a “technical explanation” and then showing “support” for this explanation in the specification, the argument is essentially rewriting and changing the plain meaning of the critical portion of the specification, col. 6, lines 33-36 and col 7, lines 44-50.

It is apparent that after the filing date the invention, as claimed, is considered enabled by applicant. The issue is whether the invention was enabled as of the filing date. The plain meaning of the passages quoted are that the invention was considered enabled only for SDA, not SDA coupled to generic “primer based” amplification.

As stated previously, the specification makes clear that should the signal primers function as amplification primers (as they would in the invention now claimed) this would lead to “high levels of background signal.”

Applicant’s arguments is merely mixing a post filing date discovery, that the invention works when coupled to generic amplification, with reassurances in the specification that apply *only* to SDA. For example, Applicant refers to col. 3 lines 57-59 as providing “support” for the technical explanation that a mispriming event is “comparatively rare” and is “detectable only after *subsequent amplification* the misprimed sequence.”

However, what the argument completely ignores is that this *subsequent amplification* is prevented, in the view of the specification, ONLY because the SDA is NOT coupled to PCR. See the entire paragraph surrounding lines 57-59. If *subsequent amplification* occurred, then there *would* be high levels of background.

In other words, the passage from the specification is further evidence that the invention was considered enabled only for the use of SDA and not SDA coupled to PCR.

The argument does not indicate where a "technical explanation" exists in the specification with respect to SDA coupled to generic "primer based" amplification. Enablement must be found in the specification or flow naturally from the disclosure in the specification.

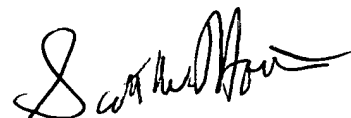
8. Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday from 8:30 AM - 3:30 PM. The examiner can also be reached on alternate Wednesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman
July 1, 2001



**SCOTT W. HOUTTEMAN
PRIMARY EXAMINER**